REMARKS

Claims 1, 2, 4, 6, 10-12, 14-16, 19, 20, 27, 35, 39, 46-48, 53, 60, and 66 are pending in the present application. Claims 35, 39, 46-48, 53, 60, and 66 are withdrawn from consideration. Claim 1 has been amended herein to recite the full name for BLASTN. Paragraph (d) of claim 1 has further been amended to more clearly describe what Applicants consider as the invention. Support for this amendment can be found in the specification at ¶16. Paragraphs (b) and (d) of claim 1 have been amended to recite that the nucleotide sequence encodes an infectious, replicating virus. Support for this amendment can be found at ¶¶5, 11, 112, and 163 of the specification as originally filed. Claim 6 has been amended to delete the redundant recitation of "an inserted nucleotide." Claim 20 has been amended to delete the reference to original paragraph (c) of claim 1. Further, claim 20 has been amended to revise the reference to paragraph (d) of claim 1 to paragraph (c) of claim 1. New claims 67-73 have been added. Support for new claims 67-70 can be found at ¶12. Support for new claim 71 and 73 can be found at ¶56. Support for new claim 72 can be found at ¶59.

No new matter has been introduced. Claims 1, 2, 4, 6, 10-12, 14-16, 19, 20, 27, 35, 39, 46-48, 53, 60, 66 to 73 are pending upon entry of the present amendment.

The sequence listing has been amended by adding two sequences, SEQ ID NOs:55 and 56. These sequences were depicted in Figure 1 of the specification as originally filed. Thus, no new matter has been introduced.

Revocation and Power of Attorney

Applicants submitted a Revocation and Power of Attorney on October 25, 2005 and requested that the Revocation and Power of Attorney be made of record in the file of the above-identified patent application. Accordingly, it is respectfully requested that all future correspondence be directed to the new Attorneys of record and that their attorney docket number be used in future correspondence from the U.S. Patent and Trademark Office.

Oath/Declaration

A new Declaration for Non-provisional Patent Application is enclosed. The alterations made by Hyun Jung Park are initialed and dated. It is respectfully requested that this Declaration be made of record in the present file.

Drawings

Two nucleotide sequences are depicted in Figure 1. These two nucleotide sequences have been added to the substitute sequence listing, which is submitted concurrently herewith. The specification has been amended herein to reflect the SEQ ID NOS. of these two sequences in Figure 1 in the corresponding figure legend.

Claim Objection

According to the Examiner's request, the acronym BLASTN has been spelled out at its first recitation in the claims. Thus, the objection to claims 1, 2, 4, 6, 10, 11, 14, 16, 19, 20 and 27 should be withdrawn.

The Rejections under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claims 1, 2, 4, 6, 10, 11, 14, 16, 19, 20, and 27 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. In particular the claims have been rejected because the claim terms "default" and "conservative" are unclear. Applicants respectfully disagree, because the specification explicitly defines the scope of these terms.

According to M.P.E.P. § 2173.05(a)(I), "[t]he meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed" (emphasis added).

With regard to the "default parameters" that are to be used for the BLASTN alignment, please note that the default parameters for the BLASTN program are defined at ¶68 of the specification as originally filed. Accordingly, the skilled artisan would exactly know what these parameters are and perform the BLASTN alignment accordingly. Because the meaning of the term "default parameters" is apparent from the specification, the rejection under 35 U.S.C. § 112, second paragraph, for indefiniteness, should be withdrawn.

Similarly, the term "conservative" is defined in the specification at ¶100. In particular, conservative amino acid exchanges are shown in Table 2, at page 31. Because the meaning of the term "conservative" is apparent from the specification, the rejection under 35 U.S.C. § 112, second paragraph, for indefiniteness, should be withdrawn.

The Rejections under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

Claims 1, 2, 4, 6, 10, 11, 14, 16, 19, 20, and 27 are rejected under 35 U.S.C. § 112, first paragraph, for insufficient written description. The claims are directed to biosequences and sequences with certain degrees of sequence identities to those biosequences. The claims have been rejected (a) because the recitation of 97.8% identity to SEQ ID NO:1 does allegedly not provide sufficient distinguishing identifying characteristics; and (b) because there is not a representative number of species in the specification.

THE LEGAL STANDARD

The test for sufficiency of written description is whether the disclosure of the application 'reasonably conveys to the artisan that the inventor had possession' of the claimed subject matter. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. (BNA) 1089, 1096 (Fed. Cir. 1983); accord *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563; *see also*, *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. (BNA) 177, 179 (Fed. Cir. 1985). The Court of Appeals for the Federal Circuit has repeatedly considered the written description requirement and consistently found that exacting detail is not necessary to meet the requirement:

> If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if [not] every nuance of the claims is explicitly described in the specification, the adequate written description requirement is met. *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996).

The criteria for determining sufficiency of written description set forth in Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶ 1, "Written Description Requirement" ("the Guidelines") (published in the January 5, 2001 Federal Register at Volume 66, Number 4, p. 1099-1111), specifies that:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see (1)(a) above), reduction to drawings (see (1) (b) above), or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the

applicant was in possession of the claimed genus (see (1)(c), above). *Id.* at p. 1106, column 3, *l.* 13-29.

Where the specification discloses any relevant identifying characteristics, *i.e.*, physical, chemical and/or functional characteristics sufficient to allow a skilled artisan to recognize the applicant was in possession of the claimed invention, a rejection for lack of written description under Section 112, first paragraph, is misplaced. *Id.*

Furthermore, in accordance with the Guidelines, what is conventional or well known to one of skill in the art need not be disclosed in detail (*Id.* at p. 1105, column 3, *ll.* 39-41), and, where the level of knowledge and skill in the art is high, a written description question should not be raised. *Id.* at p. 1106, column 1, *ll.* 34-36. See also *Capon v. Eshhar*, 418 F.3d 1349, at 1357 (Fed. Cir. 2005). See also *Invitrogen v. Clontech*, 429 F.3d 1052 (Fed. Cir. 2005).

The Rejections under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

The claimed nucleotide sequences are sufficiently described because the disclosure provides sufficient structural and functional characteristics, which are linked by a known correlation between structure and function. The specification discloses biosequences and degrees of sequence identity between the disclosed sequence and the claimed sequences. The specification further discloses that the claimed sequences, in the case of SEQ ID NO:1 and homologs thereof, encode infectious, replicating viruses, or, in the case of SEQ ID NO:2-11, are components of an infectious, replicating virus. The correlation between the structure and function of viral genomes (SEQ ID NO:1) and of the protein components of viruses (SEQ ID NO:2-11) is well-known in the art.

The specification discloses the sequence of the genome of the RSV strain 9320 (see, *e.g.*, ¶202). The specification also discloses that genomes with sequence identities of at least 97.8% sequence identity to SEQ ID NO:1 (see, *e.g.*, ¶54) are within the scope of the invention. Accordingly, the specification clearly delineates the structural boundaries of the claimed nucleotide sequences. Further, the specification discloses a function for these nucleotide sequences: they encode infectious and replicating RS viruses (see, *e.g.*, ¶¶11, 112, and 163). The correlation between the structure of a viral genome and its function, *i.e.*, to encode a virus, are well-known in the art. It is well-known to the skilled artisan which regions of the viral genome need to be maintained and which ones can be altered while

preserving the ability of the genome to encode a replicating, infectious virus. For example, the functions of the different proteins of RSV are discussed in the Background section of the present specification as filed at ¶¶5 and 6. Further, methods for the production of recombinant viruses from the claimed viral genomes are disclosed (see, *e.g.*, ¶153). Model systems for testing the resulting recombinant viruses are also disclosed (see, *e.g.*, ¶163).

Similarly, the specification discloses the amino acid sequence of the protein components of the RSV strain 9320 (see, *e.g.*, ¶49). The specification also discloses that amino acid sequences with certain minimum sequence identities to SEQ ID NOs:2-11 (see, *e.g.*, ¶63) are within the scope of the invention. Accordingly, the specification clearly delineates the structural boundaries of the claimed amino acid sequences. Further, the specification discloses a function for these nucleotide sequences: they are functional components of infectious, replicating RS viruses (see, *e.g.*, ¶¶5, 6, 11, 112, and 163). The correlation between the structure of these amino acid sequences and their function is well-known in the art. It is well known to the skilled artisan which regions of these proteins need to be maintained and which ones can be altered while preserving their function such that they can be incorporated into a replicating, infectious virus. Further, methods for the production of recombinant viruses from the claimed viral genomes are disclosed (see, *e.g.*, ¶153). Model systems for testing the resulting recombinant viruses are also disclosed (see, *e.g.*, ¶163).

In *Invitrogen*, the Federal Circuit found claims directed to modified reverse transcriptase with substantially reduced RNase H activity met the written description requirement. 429 F.3d at 1072. The court based its decision on the fact that the correlation between the RNase H activity of reverse transcriptase (function) and the reverse transcriptase gene (structure) was sufficiently known. *Id.* Further, the Federal Circuit found that *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993) was inapplicable to the situation in *Invitrogen* because the patent specification in *Fiers* did not provide the structure of even a single claimed embodiment. *Invitrogen*, 429 F.3d at 1073.

Analogously to the situation in *Invitrogen*, the present application provides a structure, *i.e.*, the nucleotide sequence of the viral genome and the amino acid sequences of the viral proteins, and a function, *i.e.*, the viral genome encodes a replicating and infectious virus and the viral proteins are components of a replicating and infectious virus. Further, the correlation between the structure of the viral genome and the function of the viral genome is well known. Similarly, the correlation between the structure of viral genes and their function is also well known.

The Examiner's comparison of the instant claims with *Fiers* is misplaced for the same reason the analogy between *Fiers* and *Invitrogen* was inapplicable—in *Fiers*, the specification provided only a reference to DNA and a method for sequencing the DNA. In contrast, the present specification provides several embodiments that fall within the scope of the claimed nuceotide sequences. These embodiments are the genomes of rg9320C4, rg9320G4, rg9320ΔG, and rg9320ΔHBS. See the specification as originally filed at ¶229.

The rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn, because Applicants have provided the structure of several working examples that fall within the scope of the claims. Further, the structure-function correlation between the viral genome and its ability to encode a replicating, infectious virus are well known in the art. Thus, Applicants have demonstrated that they were in possession of the full scope of the invention at the time of filing of the application.

The Rejections under 35 U.S.C. § 102 over Karron Should Be Withdrawn

Claims 1, 2, 4, 6, 10, 11, 16, 19, and 20 are rejected under 35 U.S.C. § 102(b) as anticipated by Karron *et al.* (1997, PNAS USA 94:13961-13966, "Karron"). In particular, the Examiner rejected the claims because Karron teaches an amino acid sequence[1] that is 99.4% identical to SEQ ID NO:9, which is recited in item (d) of the Markush group of claim 1.

THE LEGAL STANDARD

Anticipation requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee. *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F. 3d 299, 302 (Fed. Cir. 1995). An anticipating reference must describe and enable the claimed invention, including all the claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention. *In re Spada*, 911 F.2d 705 (Fed. Cir. 1990); *Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002).

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[1] The sequence is available at accession number O42050 of the NCBI database.

The standard for an anticipatory reference is set forth in *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987): "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989)(holding that "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim"). Further, the anticipating reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter. *PPG Industries, Inc. v. Guardian Industries Corp.* 75 F. 3d 1558 (Fed. Cir. 1996).

KARRON DOES NOT ANTICIPATE THE CLAIMS

The amino acid sequence taught by Karron does not fall within the genus recited in claim 1. Item (d) of the Markush group of claim 1 has been amended to recite different sequence identities. In particular for SEQ ID NO:9, only amino acid sequences that are more than 99.5% identical to SEQ ID NO:9 are within the scope of the claim. The amino acid sequence taught in Karron, however, is only 99.4% identical to SEQ ID NO:9. Thus, Karron's amino acid with the accession number O42050 does not fall within the scope of claim 1. Accordingly, Karron does not anticipate claim 1, and the rejection of claim 1 and claims 2, 4, 6, 10, 11, 16, 19, and 20, which depend from claim 1, over Karron should be withdrawn.

Conclusion

Applicants respectfully submit that all of the pending claims are now in condition for allowance. If there are any remaining concerns, the Examiner is invited to call the undersigned to schedule an interview.

It is believed that no fee is due in connection with this Amendment other than that for the extension of time; however, in the event any additional fee is required, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted, by Jacqueline Benn Reg No. 43,492

Date: April 11, 2006

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